Interview of December 4, 2002

The undersigned gratefully acknowledges the courtesies extended to herself, Gerald Swiss (Registration No. 30,113), and joint inventor Richard Greff, Ph.D., by Examiner Sharareh during the personal interview conducted on December 4, 2002 ("the Interview"). During the Interview, the outstanding claim rejections, the cited publications, and Applicants' invention were discussed. The Interview Summary provided by the Examiner accurately reflects the discussions held, which are elaborated upon below.

As was discussed at the Interview, and in Applicants' last Response, Claim 16 was amended to specify that the fluid composition portion of the claimed kit comprises a biocompatible solvent and a biocompatible polymer and that the claimed kit also comprises an endovascular prosthesis comprising a stent graft capable of inhibiting blood flow into an abdominal aortic aneurysm.

Applicants discussed at the Interview and in their last Response that the cited art does not disclose such a stent graft. It was determined at the Interview that apparently the Examiner had not previously found this information persuasive because he interpreted Applicants' claimed stent graft as but a type of either stent or graft. Applicants informed the Examiner that a *stent graft* is a unique entity – it is neither a vascular stent nor a vascular graft.

Enclosed herewith is a Declaration of co-inventor Richard J. Greff, Ph.D. In his Declaration, Dr. Greff highlights the difference between vascular stents, vascular grafts, and stent grafts. Dr. Greff asserts that a stent graft is neither a vascular stent nor a vascular graft, but is its own entity.

As explained in Dr. Greff's Declaration, a *vascular stent* is a cylindrical device that is placed intraluminally to support and keep open a vascular (arterial) blood vessel.

Vascular stents are often constructed of metal for strength and flexibility, and are designed to have an open structure or a low metal/artery ratio, which prevents occlusion and/or damage to the vascular wall. Vascular stents are often delivered intraluminally, usually over a catheter, and are positioned by balloon expansion or are self-expanding.

Vascular grafts, as explained by Dr. Greff, are natural or synthetic tubular replacements for vascular repair or replacement. Such vascular grafts may be woven, knitted, or biaxially stretched to produce fibrilliar microstructure. Vascular grafts are closed or impermeable, so as to prevent blood leakage. Vascular grafts are attached by suture in an open surgical procedure.

In contrast to either vascular stents or vascular grafts, *stent grafts* are devices that contain: (1) a vascular graft to repair or replace the diseased blood vessel, and (2) a stent for fixation and sealing of the ends of the device, intraluminally. A stent graft is placed intraluminally over a catheter and anchored in the blood vessel by expansion (self expansion or by balloon expansion) of the stent portion(s) of the device. The graft portion of the stent graft contains blood flow and excludes the diseased portion of the blood vessel. Such stent grafts come in several configurations, including straight, tapered, and bifurcated. Stent grafts are most successful in the treatment of abdominal aortic aneurysm disease. Stent grafts may be referred to as *endovascular grafts* due to the nature of their placement.

Dr. Greff declares that the differences between vascular stents, vascular grafts, and stent grafts were known and appreciated by those in the art at the time Applicants' invention was made.

It is with this knowledge of vascular stents, vascular grafts, and stent grafts that Applicants respectfully request reconsideration of the subject application.

Yamaguchi Publication

Subsequent to the Interview, Examiner Sharareh brought to Applicants' attention the publication *Embolization of Perigraft Leaks after Endovascular Stent-Graft Treatment of Distal Arch Anastomotic Pseudoaneurysm with Coil and n-Butyl 2-Cyanoacrylate* by Yamaguchi *et al.* As requested, this publication has been considered by Applicants.

Rejections Under 35 U.S.C. § 102(b) Over U.S. Patent No. 5,702,361 to Evans et al.

Claims 16 and 20-29 stand rejected under 35 U.S.C. § 102(b) as allegedly anticipated by U.S. Patent No. 5,702,361 to Evans et al. ("Evans"). These rejections are respectfully traversed.

To anticipate a claim, a single source must contain all of the elements of the claim. *Hybritech Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1379 (Fed. Cir. 1986). Missing elements may not be supplied by the knowledge of one skilled in the art or the disclosure of another reference. *Structural Rubber Prods. Co. v. Park Rubber Co.*, 749 F.2d 707, 716 (Fed. Cir. 1984). Claims 16 and 20-29 each contain the requirement that the kit contain an endovascular prosthesis comprising a stent graft capable of inhibiting blood flow into an abdominal aortic aneurysm. Therefore, for Evans to anticipate Claims 16 and 20-29, it must contain Applicants' stent graft element. It does not.

As discussed in Applicants' prior Response, there is no disclosure in Evans of using any endovascular prosthesis capable of inhibiting blood flow into an abdominal aortic aneurysm, let alone a stent graft capable of inhibiting blood flow into an abdominal aortic aneurysm. This fact is reiterated in Dr. Greff's Declaration. *See Greff Declaration, ¶ 5.* In light of the fact that Evans does not contain all elements of Applicants' claimed kits, the 35 U.S.C. § 102(b) rejections are in error. Applicants respectfully request withdrawal of these rejections.

Rejections Under 35 U.S.C. § 103(a) Over U.S. Patent No. 5,443,454 to Tanabe In View of U.S. Patent No. 5,749,894 to Engelson and U.S. Patent No. 5,695,480 to Evans

Claims 16 and 20-29 stand rejected under 35 U.S.C. § 103(a) as allegedly obvious over U.S. Patent No. 5,443,454 to Tanabe et al. ("Tanabe") in view of U.S. Patent No. 5,749,894 to Engelson ("Engelson") and U.S. Patent No. 5,695,480 to Evans et al. ("Evans II"). These rejections are respectfully traversed.

When applying 35 U.S.C. § 103, four tenets of patent law must be adhered to: (1) the claimed invention must be considered as a whole, (2) the references must be considered as a whole and must suggest the desirability and thus the obviousness of making the combination, (3) the references must be viewed without the benefit of impermissible hindsight vision, and (4) a reasonable expectation of success is the standard with which obviousness is determined. *See MPEP § 2141*, citing *Hodosh v. Block Drug Co., Inc.*, 786 F.2d 1136, 1143 (Fed. Cir. 1986). Moreover, to establish a *prima facie* case of obviousness, three basic criteria must be met: (1) there must be some suggestion or motivation to modify the reference or to combine reference teachings, (2) there must be a reasonable expectation of success, and (3) the prior art reference(s) must teach or suggest all of the claim limitations. *See MPEP § 2142.* Applicants respectfully assert that these tests of obviousness have not been met in this case.

Applicants maintain that a *prima facie* case of obviousness has not been established because there is no suggestion or motivation, outside Applicants' own disclosure, to modify the Tanabe publication as suggested by the Examiner. The Examiner admits that Tanabe does not teach a kit for practicing embolectomy containing a prosthesis.[1] *See Final Official Action, Page 3.* Therefore, Tanabe does not teach a kit containing a prosthesis comprising a stent graft capable of inhibiting blood flow into an abdominal aortic aneurysm. Because

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[1]Applicants wish to respectfully point out that Tanabe does not disclose kits for practicing embolectomy, as suggested by the Examiner. Embolectomy refers to the process of *removing* an embolus or plug. Tanabe is not removing an embolus, but instead is *forming* an embolus.

Tanabe is silent as to this claimed element, in order to sustain the 35 U.S.C. § 103(a) rejections, the Examiner must provide some suggestion or motivation to modify Tanabe. The Examiner has stated only that "it would have been obvious to one or ordinary skill in the art at the time of invention, to prepare a kit comprising Tanabe's liquid substance, and Tanabe's catheter, with a prosthetic device such as those taught by Engelson, because as taught by Tanabe's patent itself, the catheter can be employed in a prosthetic method for treatment of aneurysm." *See Official Action Mailed March 13, 2002, Pages 3-4.* Applicants respectfully maintain that this is conclusory and insufficient motivation to modify Tanabe as suggested by the Examiner.

Engelson teaches a variety of vaso-occlusive devices, but does not disclose Applicants' claimed stent graft capable of inhibiting blood flow into an abdominal aortic aneurysm. As discussed in Dr. Greff's Declaration, stent grafts are unique entities. Therefore, even if one were somehow prompted to combine the vaso-occlusive devices of Engelson with the catheter of Tanabe, he would not arrive at Applicants' invention. Applicants reiterate that there is nothing in or suggested by Tanabe and/or Engelson which would either prompt one to modify the publications, as suggested by the Examiner, or to lead one to believe he would succeed in arriving at the claimed invention. *See, e.g., Page 8 of Applicants' Response filed July 15, 2002.*

Evans II does not cure the individual or combined deficiencies of Tanabe and Engelson. Evans II, like Tanabe, fails to disclose any endovascular prosthesis, let alone an endovascular prosthesis comprising a stent graft capable of inhibiting blood flow into an abdominal aortic aneurysm.

Due to at least these deficiencies in Tanabe, Engelson, and Evans II, the *prima facie* obviousness analysis fails. Not all of the claimed limitations are found within Tanabe, Engelson, and Evans II. Therefore, the third requirement for showing *prima facie* obviousness has not been met. The omission of certain elements from the cited publications, especially the absence of any disclosure to a stent graft capable of inhibiting blood flow into an abdominal aortic aneurysm, also precludes the publications from

satisfying the first requirement for showing *prima facie* obviousness – motivating one or suggesting to one to modify Tanabe. Finally, because not all claimed elements are present, one of skill in the art would not have reasonably expected to succeed in arriving at Applicants' kits – the second requirement for showing *prima facie* obviousness. Together, a *prima facie* case of obviousness has not been made out.

CONCLUSION

In summary, Applicants maintain that the outstanding rejections have been obviated. From the foregoing, further and favorable action in the form of a Notice of Allowance is respectfully requested and such action is earnestly solicited.

In the event that there are any questions relating to this response, or the application in general, it would be greatly appreciated if the Examiner would telephone the undersigned attorney concerning such questions so that the prosecution of this application may be expedited.

Respectfully submitted,
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